DEPARTMENT OF HEALTH AND HUMAN SERVICES

OMB

Food and Drug Administration

21 CFR Part 1271

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[Docket No. 97N–484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; correction

SUMMARY: The Food and Drug Administration (FDA) is correcting an interim final rule that published in the **Federal Register** on January 27, 2004 (69 FR 3823). The interim final rule excepted human dura mater and human heart valve allografts, currently subject to application or notification requirements under the Federal Food, Drug, and Cosmetic Act from the scope of the definition of "human cells, tissues, or cellular or tissue-based products (HCT/P's)" subject to the registration and listing requirements contained in 21 CFR Part 1271. That definition became effective on January 21, 2004. The interim final rule published with some errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

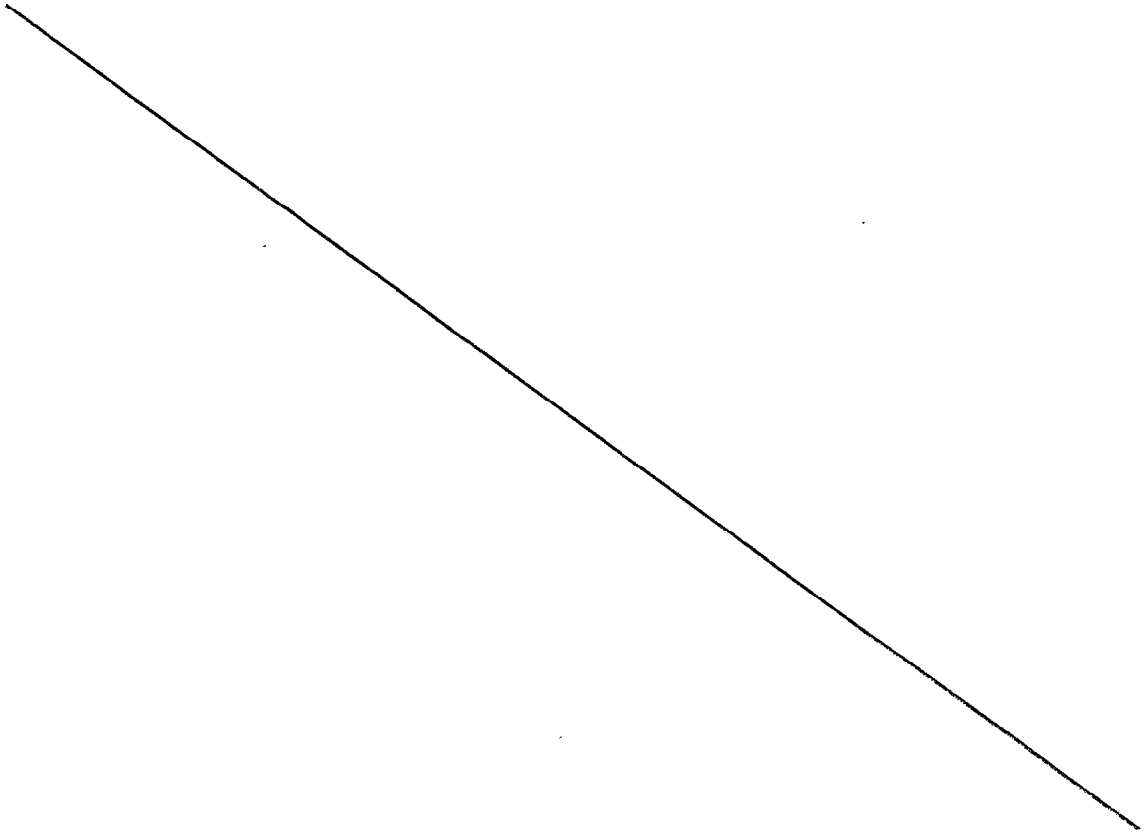
SUPPLEMENTARY INFORMATION: In the FR Doc. 04–1733, appearing on page 3824 in the **Federal Register** of Tuesday, January 27, 2004, the following corrections are made:

NCR 1

1. On page 3824, in the **DATES** section, by removing the sentence "The compliance date is March 29, 2004."

2. On page 3824, under **SUPPLEMENTARY INFORMATION** in the I. Background section, the phrase "FDA understands that many establishments may have reasonably expected FDA to delay the effective date of this provision again, since the donor suitability and GTP rules are not yet finalized" is revised to read:

"FDA understands that many establishments may have reasonably expected FDA to delay the effective date of this provision again, since the donor suitability and GTP rules are not yet finalized. Accordingly, FDA expects that affected firms will be in compliance with these requirements by March 29, 2004, and not on January 21, 2004, the effective date of the definition regulation."



Dated: 1/29/04

cb043

January 29, 2004.

William Hubbard

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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